

INTEGRATIVE THERAPEUTICS INC."

NF Formulas PhytoPharmica Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503 582.8386 F: 503 582,0467

ENZYMATIC THERAPY PHYTOPHARMICA

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920 469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 F 920.469.4418 (Phyto)

What Better feels like"

June 23, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE.

Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory ın nature.

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Recancostat®	On of the most powerful antioxidant inside your body is GSH, which is required by both your immune and detoxification systems.*	L-Glutathione, Reduced, AnthoRedoxin™ standardized to contain 10% anthocyanins, Beet (Beta vulgaris) Root Extract, Bilberry (Vaccinium myrtillus) Fruit Extract, Black Currant (Ribes nigrum) Berry Extract, European Elder (Sambucus nigra) Berry Extract, L-Cysteine

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 6/23/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608

Sincerely,

Michael P. Devereux Chief Financial Officer 975 0162

LET 16448



INTEGRATIVE THERAPEUTICS INC."

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PHYTOPHARMICA'

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 F: 503.582.0467 825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 f: 920.469.4418 (Phyto)

ENZYMATIC THERADY

What Better feels like™

June 23, 2005

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Recancostat®	Maintain healthy levels of GSH and antioxidants inside your body is essential to support your cellular immune function.*	L-Glutathione, Reduced, AnthoRedoxin™ standardized to contain 10% anthocyanins, Beet (Beta vulgaris) Root Extract, Bilberry (Vaccinium myrtillus) Fruit Extract, Black Currant (Ribes nigrum) Berry Extract, European Elder (Sambucus nigra) Berry Extract, L-Cysteine

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Robert Doster

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Recancostat®	Recancostat is the only oral source of GSH that's shown to increase your body's levels of this powerful antioxidant and substantially support your cellular immune response.*	L-Glutathione, Reduced, AnthoRedoxin™ standardized to contain 10% anthocyanins, Beet (Beta vulgaris) Root Extract, Bilberry (Vaccinium myrtillus) Fruit Extract, Black Currant (Ribes nigrum) Berry Extract, European Elder (Sambucus nigra) Berry Extract, L-Cysteine

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By:	
	Robert Doster
Title:	Senior Vice President of Scientific Affairs

Date 6/23/05

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June 24, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway
College Park, MD 20740

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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Recancostat®	This exclusive patented formula contains an effective combination of ingredients to maintain the right amount of GSH and antioxidants your body needs.*	L-Glutathione, Reduced, AnthoRedoxin™ standardized to contain 10% anthocyanins, Beet (Beta vulgaris) Root Extract, Bilberry (Vaccinium myrtillus) Fruit Extract, Black Currant (Ribes nigrum) Berry Extract, European Elder (Sambucus nigra) Berry Extract, L-Cysteine

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Date 6/24/05

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June 24, 2005

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Recancostat®	AnthoRedoxin [™] - an exclusive blend of potent fruit antioxidants called anthocyanins, which help maintain the efficacy of GSH.*	L-Glutathione, Reduced, AnthoRedoxin™ standardized to contain 10% anthocyanins, Beet (Beta vulgaris) Root Extract, Bilberry (Vaccinium myrtillus) Fruit Extract, Black Currant (Ribes nigrum) Berry Extract, European Elder (Sambucus nigra) Berry Extract, L-Cysteine

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By: KLICILL

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date 6/24/65

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What Better feels like™

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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Recancostat®	Glutathione exists in your body in both a reduced and oxidized state, but it's the reduced state that carries out a broad range of important functions including detoxification and immune function.*	L-Glutathione, Reduced, AnthoRedoxin™ standardized to contain 10% anthocyanins, Beet (Beta vulgaris) Root Extract, Bilberry (Vaccinium myrtillus) Fruit Extract, Black Currant (Ribes nigrum) Berry Extract, European Elder (Sambucus nigra) Berry Extract, L-Cysteine

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Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 6/24/05

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ENZYMATIC THERAPY

w*'hat Better* feels like~

June 24, 2005

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Recancostat®	AnthoRedoxin and Glutathione are also essential to cellular detoxification, normal immune function, DNA production and repair, and recycling of antioxidant vitamins E and C.*	L-Glutathione, Reduced, AnthoRedoxin™ standardized to contain 10% anthocyanins, Beet (Beta vulgaris) Root Extract, Bilberry (Vaccinium myrtillus) Fruit Extract, Black Currant (Ribes nigrum) Berry Extract, European Elder (Sambucus nigra) Berry Extract, L-Cysteine

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Ву:		

Robert Doster

Title Senior Vice President of Scientific Affairs

6/24/05

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Recancostat®	Supplementing with Recancostat helps recycle oxidized GSH to its reduced state and maintain its anticxidant power.*	L-Glutathione, Reduced, AnthoRedoxin™ standardized to contain 10% anthocyanins, Beet (Beta vulgaris) Root Extract, Bilberry (Vaccinium myrtillus) Fruit Extract, Black Currant (Ribes nigrum) Berry Extract, European Elder (Sambucus nigra) Berry Extract, L-Cysteine

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Robert Doster

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June 25, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE Label Claims/Disclaimers

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Recancostat®	Supplementing with Recancostat® helps stabilize and maintain beneficial levels of reduced GSH.*	L-Glutathione, Reduced, AnthoRedoxin™ standardized to contain 10% anthocyanins, Beet (Beta vulgaris) Root Extract, Bilberry (Vaccinium myrtillus) Fruit Extract, Black Currant (Ribes nigrum) Berry Extract, European Elder (Sambucus nigra) Berry Extract, L-Cysteine

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By: Robert Doster

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Sincerely.

Michael P. Devereux Chief Financial Officer

Recancostat 14e



INTEGRATIVE THERAPEUTICS INC."

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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Recancostat®	Reduced GSH – A potent antioxidant that detoxifies and helps eliminate free radicals.* GSH is vital for support of immune function and general health.*	L-Glutathione, Reduced, AnthoRedoxin™ standardized to contain 10% anthocyanins, Beet (Beta vulgaris) Root Extract, Bilberry (Vaccinium myrtillus) Fruit Extract, Black Currant (Ribes nigrum) Berry Extract, European Elder (Sambucus nigra) Berry Extract, L-Cysteine

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Recancostat®	It is essential that your body maintain a sufficient amount of GSh to support its cellular immune function.*	L-Glutathione, Reduced, AnthoRedoxin™ standardized to contain 10% anthocyanins, Beet (Beta vulgaris) Root Extract, Bilberry (Vaccinium myrtillus) Fruit Extract, Black Currant (Ribes nigrum) Berry Extract, European Elder (Sambucus nigra) Berry Extract, L-Cysteine

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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Recancostat®	Supplementing with Recancostat has been clinically shown to increase circulating concentrations of GSH and promote healthy immune function.*	L-Glutathione, Reduced, AnthoRedoxin™ standardized to contain 10% anthocyanins, Beet (Beta vulgaris) Root Extract, Bilberry (Vaccinium myrtillus) Fruit Extract, Black Currant (Ribes nigrum) Berry Extract, European Elder (Sambucus nigra) Berry Extract, L-Cysteine

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Recancostat®	In a scientific study, oral supplementation with Recancostat significantly increased circulating levels of glutathione – the body's own natural antioxidant.*	L-Glutathione, Reduced, AnthoRedoxin™ standardized to contain 10% anthocyanins, Beet (Beta vulgaris) Root Extract, Bilberry (Vaccinium myrtillus) Fruit Extract, Black Currant (Ribes nigrum) Berry Extract, European Elder (Sambucus nigra) Berry Extract, L-Cysteine

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RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Recancostat®	AnthoRedoxin™ - An exclusive preparation of anthocyanins that helps protect GSH from oxidation and recycles oxidized GSH back to reduced GSH.*	L-Glutathione, Reduced, AnthoRedoxin™ standardized to contain 10% anthocyanins, Beet (Beta vulgaris) Root Extract, Bilberry (Vaccinium myrtillus) Fruit Extract, Black Currant (Ribes nigrum) Berry Extract, European Elder (Sambucus nigra) Berry Extract, L-Cysteine

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: ______Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 6/25/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608

Sincerely,



INTEGRATIVE THERAPEUTICS INC."

NF Formulas PhytoPharmica
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 F 503.582.0467

ENZYMATIC THERAPY & PHYTOPHARMICA'

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P· 920.469.9099 F: 920.469.4418 (Phyto)

ENZYMATIC THERAPY

What Better feels like"

June 25, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE:

Label Claims/Disclaimers

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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Recancostat®	L-Cysteine – An amino acid which helps protect GSH and functions as a GSH building block.*	L-Glutathione, Reduced, AnthoRedoxin™ standardized to contain 10% anthocyanins, Beet (Beta vulgaris) Root Extract, Bilberry (Vaccinium myrtillus) Fruit Extract, Black Currant (Ribes nigrum) Berry Extract, European Elder (Sambucus nigra) Berry Extract, L-Cysteine

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Ву:			KI	J)	J 17	
	 	 				_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 6/25/05

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What Better feels like"

June 27, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway
College Park, MD 20740

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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM
	3	REFERS
Recancostat®	Clinically studied for nutritional	L-Glutathione, Reduced, AnthoRedoxin™
	support of healthy immune	standardized to contain 10% anthocyanins,
	function.*	Beet (Beta vulgaris) Root Extract, Bilberry
		(Vaccinium myrtillus) Fruit Extract, Black
		Currant (Ribes nigrum) Berry Extract,
		European Elder (Sambucus nigra) Berry
		Extract, L-Cysteine

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: KLICILL

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 6/27/05

11 you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608

Sincerely,



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NF Formulas PhytoPharmica
Tyler Encapsulations Vitaline Formulas

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What Better feels like"

June 27, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810
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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Recancostat®	Oral form clinically studied to be absorbed and increase serum levels of GSH.*	L-Glutathione, Reduced, AnthoRedoxin™ standardized to contain 10% anthocyanins, Beet (Beta vulgaris) Root Extract, Bilberry (Vaccinium myrtillus) Fruit Extract, Black Currant (Ribes nigrum) Berry Extract, European Elder (Sambucus nigra) Berry Extract, L-Cysteine

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

RUPLE RUPLE

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 6/21/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608

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